PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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INSIGHT INTELLECTUAL PROPERTY
LIMITED
WANG,Dazuo

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43 *bis*.1)

Date of mailing (*day/month/year*)
29 SEP 2005 (29-09-2005)

Applicant's or agent's file reference	FOR FURTHER ACTION
05PCT0132	see paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/CN2005/000508	15.Apr 2005(15.04.2005)	15.Apr 2004(15.04.2004)

International Patent Classification (IPC) or both national classification and IPC
INC7:C129/10,9/02,15/12,15/28,C12Q1/68

Applicant
THE CHINESE UNIVERSITY OF HONG KONG et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No.II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i)with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No.VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No.VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CN	Date of completion of this opinion	Authorized officer
The State Intellectual Property Office, the P.R.China 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088	01.Sep 2005(01.09.2005)	K.E.Ke
Facsimile No. 86-10-62019451		Telephone No. 86-010-62085090

Form PCT/ISA/237(cover sheet)(April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CN2005/000508

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed
   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :

   a. type of material
      ☐ a sequence listing
      ☐ table(s) related to the sequence listing

   b. format of material
      ☐ on paper
      ☐ in electronic form

   c. time of filing/furnishing
      ☐ contained in the international application as filed
      ☐ filed together with the international application in electronic form
      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No.III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

This questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious),or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-8

because:

☒ the said international application, or the said claims Nos. 1-8
relate to the following subject matter which does not require an international preliminary examination(*specify*):
methods for the diagnosis or for the treatment of diseases

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 1-8

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☒ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees:

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with
   ☒ not complied with for the following reasons:
   Each of claims 9-18 comprises many embodiments that lack the same or corresponding special technical features. For example, the arrays or kits prepared with one of said 5 genes respectively, have not a common structural unit(or component)each other. Therefore, claims 9-18 lack unity in rule(13) of PCT.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos. _____

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International application No. PCT/CN2005/000508

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement:

Novelty (N)	Claims	9-18	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	9-18	NO
Industrial applicability (IA)	Claims	9-18	YES
	Claims		NO

2. Citations and explanations

The followed documents are cited in the report:

D1: J. Clin. Invest., 1997,100(4), Pei, York et al:" Association of angiotensinogen gene T235 variant with progression of immunoglobulin A nephropathy in Caucasian patients"

D2: Diabetes Care,2003,26(8), Wang, Ying et al:" Phenotypic heterogeneity and associations of two aldose reductase gene polymorphisms with nephropathy and retinopathy in type 2 diabetes."

D3: Kidney International, 2000,58(2), 783-789, Shu, Kuo-Hsiung et al:" Impact of interleukin-1 receptor antagonist and tumor necrosis factor-a gene polymorphism on IgA nephropathy"

About novelty:

Claims 9-18 ask for protection of the array or kit comprising some genes or primers. Though some of the genes are disclosed in D1-D3,the array or kit are not disclosed in D1-D3.Claims 9-18 are novel and meet the criteria mentioned in article 33(2)PCT.

About inventiveness:

Claims 9-16 ask for protection of the array or kit comprising at least one polymorphic sequence selected from the group consisting of :an I/D genotype of an ACE gene etc. However,D1-D3 have disclosed such polymorphic sequences of these genes and the relation between some diseases and them.So the array or the kit comprising one of such sequences are obvious to the person skilled in the relevant field of technology in light of D1-D3.Claims 9-16 don't appear to be inventive and don't appear to meet the criteria mentioned in article 33(3)PCT.

Claims 17-18 ask for protection of the kit for detecting a subject of Chinese diabetic suffering from,at risk for developing or suspected of suffering from anephropathy comprising:primers for amplifying the gene ACE,AGT,ALR2 or TNF-α. D1-D3 have disclosed such genes all play important roles in nephropathy.So the combination of them for detecting nephropathy is obvious.Designing primers for the disclosed gene are a common knowledge of the relevant technical field.Thus The kit comprising the primers for these genes are obvious to the person skilled in the relevant field of technology.Claims 17-19 don't appear to be inventive and don't appear to meet the criteria mentioned in article 33(3)PCT.

About industrial applicability:

The techinical solutions of claims 9-18 can be used in diagnosis of diseases.Thus claims 9-18 possess industrial applicability and meet the criteria mentioned in article 33(4)PCT.